



#14
m.m.
8/12/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
LABERGERIE ERIK ET AL.)
Serial No.09/819,496) Art Unit: 1615
Filed: March 28, 2001) Examiner: R.M. JOYNES

FOR: PULVERULENT MANNITOL AND PROCESS FOR PREPARING IT

DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks
Washington, D.C.

Sir:

I, Philippe LEFEVRE, of 54, route de Merville,
59400 MERVILLE, France, do solemnly declare:

THAT I am a graduate of "Ecole Nationale Supérieure
de Chimie" - 59000 LILLE - FRANCE

THAT I have been working as chemical engineer since
the 28th of January, 1985 and that I now hold the
position of manager of the Pharmaceutical and Cosmetic
Applications Department by ROQUETTE FRERES;

THAT I am a named inventor on the present patent
application n° 09/819,496, I am fully familiar therewith
and I am competent to give an opinion regarding the
techniques and subject matter thereof;

THAT the operating instructions entitled "POWDER
CHARACTERISTICS TESTER OPERATING INSTRUCTIONS" from
HOSOKAWA IRON WORKS, LTD. OSAKA, JAPAN and provided with
the letter dated November 11, 2001, came to my knowledge
before the filing of the present application;

THAT I used said operating instructions for
measuring the packed bulk density of the pulverulent
mannitol of the present application;

THAT, said operating instructions were also widely used by the person skilled in the art using the HOSOKAWA apparatuses before and at the time of the filing of the present application;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 24/06/02

LEFEVRE Philippe

A handwritten signature in black ink, appearing to be 'C. Lefevre', with a stylized flourish at the end.



ANNEX I

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of)
LABERGERIE ERIK ET AL.)
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To Honorable Commissioner of Patents and Trademarks
Washington, D.C.

Sir:

I, Philippe LEFEVRE, of 54, route de Merville,
59400 MERVILLE, France, do solemnly declare:

THAT I am a graduate of "Ecole Nationale de chimie"
- 59000 LILLE - France;

THAT I have been working as chemical engineer since
the 28th of January 1985, and that I now hold the
position of manager of the Pharmaceutical and Cosmetic
Applications Department by ROQUETTE FRERES;

THAT I am well acquainted in the chemistry of
sugars and in particular in the field of pulverulent
mannitol ;

THAT I am a named inventor on the present patent
application n° 09/819,496, I am fully familiar therewith
and I am competent to give an opinion regarding the
techniques and subject matter thereof;

THAT I have read and understood the Office Action
mailed on March 18, 2002 in connection with the present
patent application;

THAT I have also read and understood US Patent
n° 5,573,777 to Serpelloni et al., in particular the
examples of said patent;

THAT I routinely perform measurements of packed bulk density on pulverulent mannitols;

THAT I performed the tests joined in annex which clearly show that the pulverulent mannitol of the invention differs in its structure and properties from the pulverulent mannitol of Serpelloni et al. and that this difference allows new applications such as the filling of hard capsules in the pharmaceutical field;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

16/07/02

LEFEVRE Philippe



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 July 18, 2002

ANNEX II

**TABLE COMPARING THE CHARACTERISTICS OF THE
 PULVERULENT MANNITOL OF THE INVENTION WITH THE
 MANNITOL OF SERPELLONI ET AL.**

	PULVERULENT MANNITOL OF THE INVENTION		PULVERULENT MANNITOL OF SERPELLONI ET AL	
	Lab 2695 Sample X0201	Lab 2695 Sample X0104	PEARLITOL 200 SD Sample E455M	PEARLITOL 100 SD Sample E272 M
Packed bulk density	<u>0.72</u>	<u>0.71</u>	0.54	0.58
Flow factor HOSOKAWA	76	65	81	79
Rate of dissolution in water of the fraction 100 – 200 µm	20 s	20 s	< 10 s	< 10 s
Rate of dissolution in water	40 s	40 s	< 10 s	< 10 s
Average diameter (Laser particle size analysis)	178 µm	126 µm	174 µm	101 µm



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ANNEX III

ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF THE INVENTION - REF LAB 2695 - SAMPLE X0104

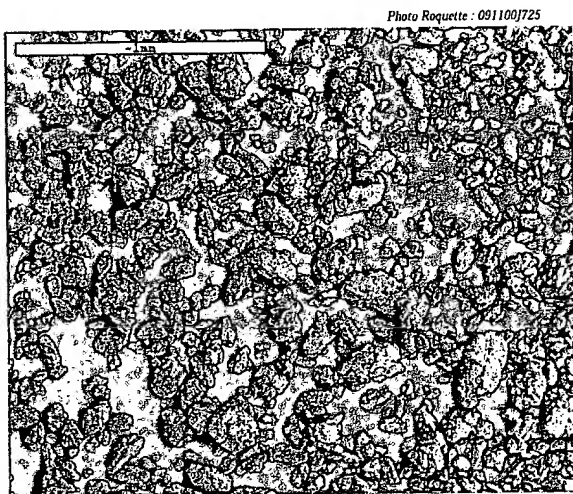


Photo 1: Lab 2695 sample X0104
Magnification: 38.5 X



Photo 2: Lab 2695 sample X0104
Magnification: 154 X

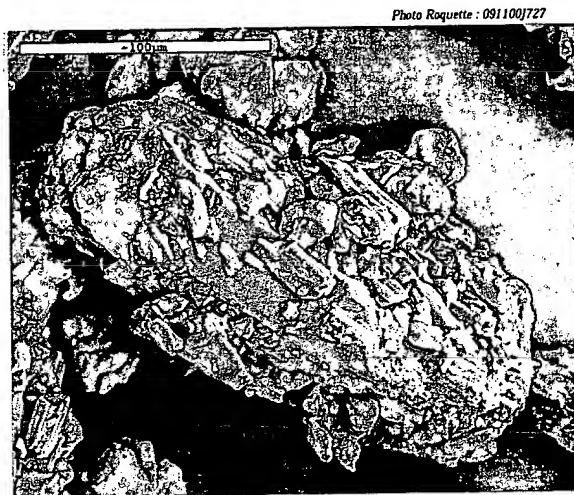


Photo 3: Lab 2695 sample X0104
Magnification: 385 X



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ANNEX IV

ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF THE INVENTION - REF LAB 2695 - SAMPLE X201

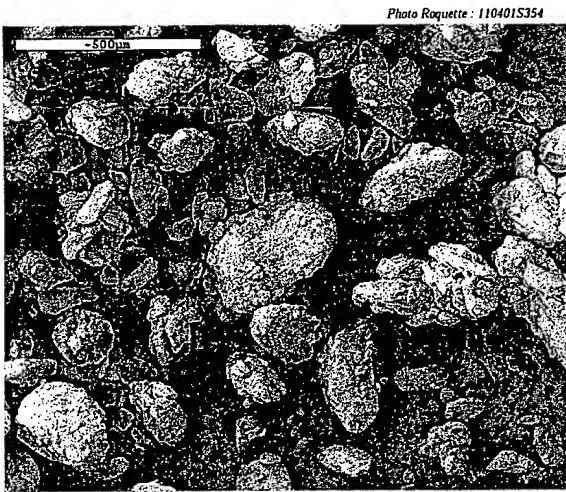


Photo 1: Lab 2695 sample X201
Magnification: 57.5 X

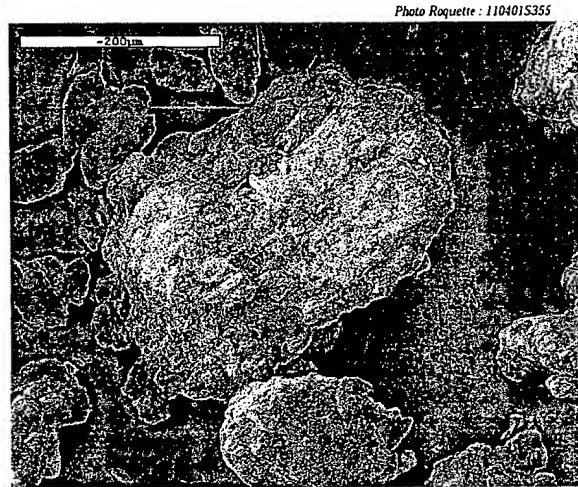


Photo 2: Lab 2695 sample X201
Magnification: 154 X

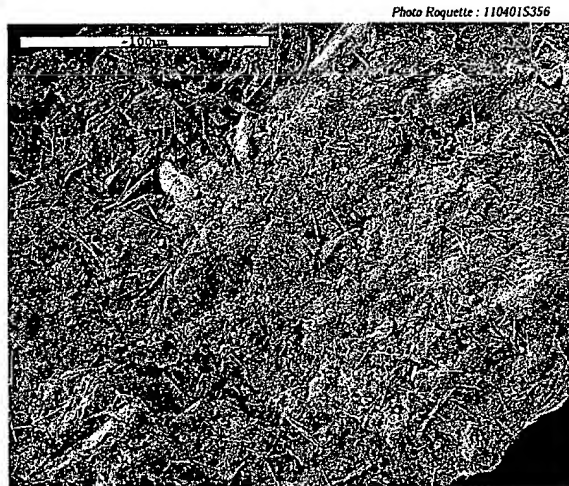


Photo 3: Lab 2695 sample X201
Magnification: 385 X



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ANNEX V

ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF SERPELLONI - PEARLITOL ® SD 100 - REF LAB 2515

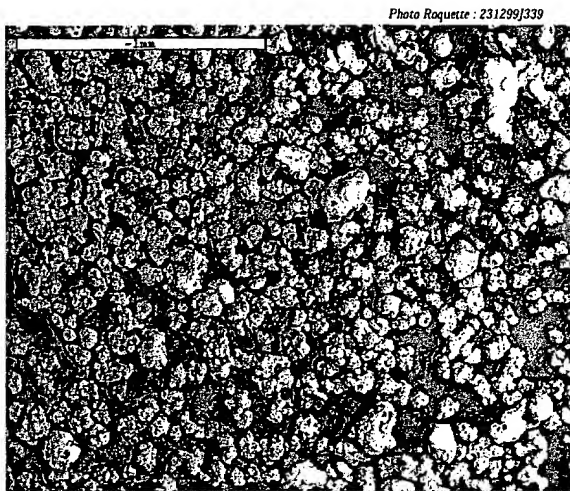


Photo 1: Pearlitol ® SD100 - Lab 2515
Magnification: 38.5 X

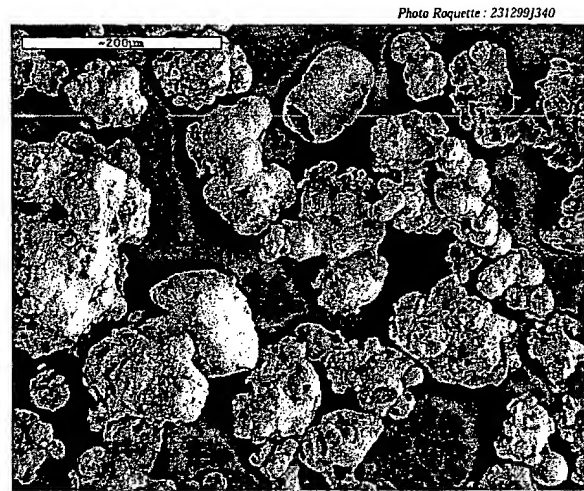


Photo 2: Pearlitol ® SD100 - Lab 2515
Magnification: 154 X



Photo 3: Pearlitol ® SD100 - Lab 2515
Magnification: 385 X



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ANNEX VI

ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF SERPELLONI - PEARLITOL ® SD 200 REF LAB E138M

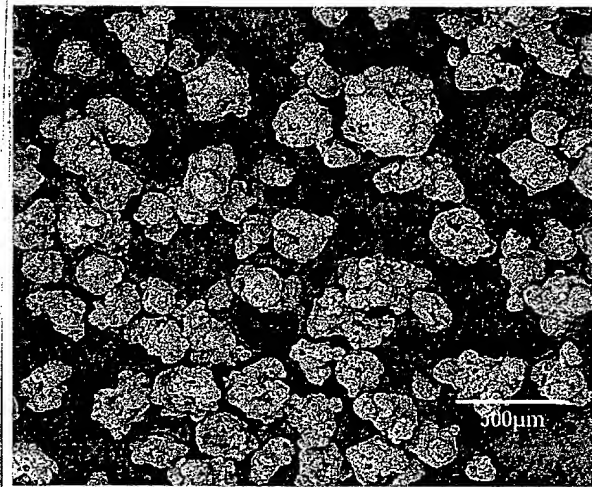


Photo 1: Pearlitol ® SD200 - Sample E138M
Magnification: 35 X

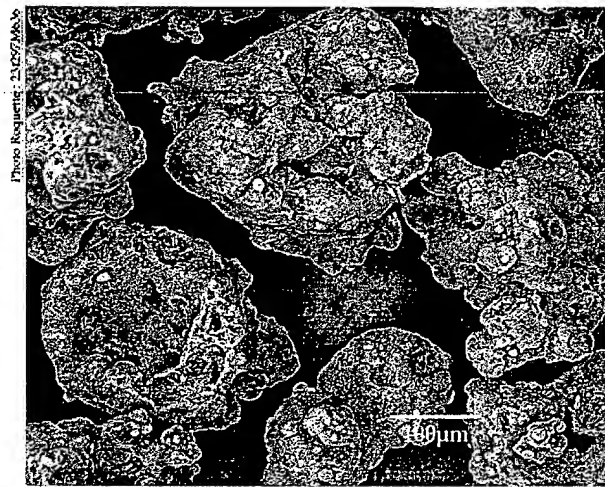


Photo 2: Pearlitol ® SD200 - Sample E138M
Magnification: 146 X

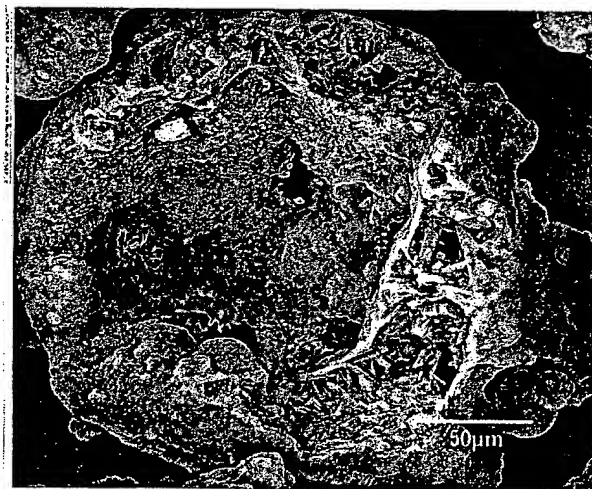


Photo 3: Pearlitol ® SD200 - Sample E138M
Magnification: 365 X